

COMPOSITION FOR DELIVERING BIOACTIVE AGENTS FOR IMMUNE RESPONSE AND ITS PREPARATION

REFERENCE TO CO-PENDING APPLICATION

This application is a continuation of application Ser. No. 07/629,138, filed Dec. 18, 1990, abandoned, which is a continuation-in-part of application Ser. No. 07/325,193, filed Mar. 16, 1989, abandoned, which is a continuation-in-part of application Ser. No. 07/169,973, filed Mar. 18, 1988, U.S. Pat. No. 5,075,109, which is a continuation-in-part of application Ser. No. 06/923,159, filed Oct. 24, 1986, abandoned.

This invention was made with government support under Contract No. DAMD17-86-C-6162 awarded by the Department of the Army of the United States Government. The U.S. Government has certain non-commercial rights in the invention. The U.S. Government does not have rights in the invention pertaining to drug delivery.

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BACKGROUND OF THE INVENTION

This invention relates to a method and a formulation for orally administering a bioactive agent encapsulated in one or more biocompatible polymer or copolymer excipients, preferably a biodegradable polymer or copolymer, affording microcapsules which due to their proper size and physical chemical properties results in the microcapsules and contained agent reaching and being effectively taken up by the folliculi lymphatic aggregati, otherwise known as the "Peyer's patches", of the gastrointestinal tract in an animal without loss of effectiveness due to the agent having passed through the gastrointestinal tract. Similar folliculi lymphatic aggregati can be found in the respiratory tract, genitourinary tract, large intestine and other mucosal tissues of the body such as ophthalmic tissues. Hereafter, the above-described tissues are referred to in general as mucosally-associated lymphoid tissues.

The use of microencapsulation to protect sensitive bioactive agents from degradation has become well-known. Typically, a bioactive agent is encapsulated within any of a number of protective wall materials, usually polymeric in nature. The agent to be encapsulated can be coated with a single wall of polymeric material (microcapsules), or can be homogeneously dispersed within a polymeric matrix (microspheres). (Hereafter, the term microcapsules refers to both microcapsules and microspheres). The amount of agent inside the microcapsule can be varied as desired, ranging from either a small amount to as high as 95% or more of the microcapsule composition. The diameter of the microcapsule can also be varied as desired, ranging from less than one micrometer to as large as three millimeters or more.

Peyer's patches are aggregates of lymphoid nodules located in the wall of the small intestine, large intestine and appendix and are an important part of body's defense against the adherence and penetration of infectious agents and other